REMARKS

Claim 1-45 are pending in the application. Claims 1-17, 19-38, and 42-45 are rejected. Claims 18 and 39-41 are withdrawn from consideration.

Specification

The abstract has been objected to because it exceeds 150 words in length and is not limited to a single paragraph. Applicant's amendments to the abstract are believed to overcome this objection.

Claim Rejections - 35 U.S.C. § 112

Claims 35, 36, and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

With regard to claim 42, the Examiner is correct in that it should depend upon claim 39, which has been withdrawn from consideration. Applicant therefore withdraws claim 42 from consideration.

With regard to claims 35 and 36, Applicant respectfully submits that the claims are not indefinite. "Breadth of a claim is not to be equated with indefiniteness." M.P.E.P. § 2173.04 (citing *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (CCPA 1971)). Although these claims do not recite specific geographical boundaries, it is clear that in claim 35 the user processors are located in the same geographical area in which the main processor and database are located, and in claim 36 the subsidiary processors and databases are located in geographical areas that are different from the one in which the main processor and database are located. Thus, claims 35 and 36 are sufficiently definite. Reconsideration and withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 6, 7, 11, 13, and 43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon et al. (U.S. Patent No. 5,991,731 in view of DeBusk et al. (U.S. Patent No. 5,995,937). Claims 2-5, 15-17, 19-24, 28, 32-38, and 44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon and DeBusk, as applied to claims 1, 19, and 43, and further in view of Edelson et al. (U.S. Patent No. 5,737,539). Claims 25-27, 29, 30, 42, and 45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon, DeBusk, and Edelson, as applied claim 19, and further in view of Umen et al. (U.S. Patent No. 5,734,883). Claims 8-10 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon in view of Debusk, as applied to claim 1, and further in view of Umen. Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon in view of Debusk, as applied to claim 1, and further in view of Official Notice. Claim 31 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Colon, Debusk, Edelson, and Umen, as applied to claim 25, and further in view of Official Notice. Applicant respectfully traverses these rejections for the reasons set forth below.

The present invention is directed to the design of clinical trials. For example, claims 1-17 require a main database of information concerning prior clinical trials in the form of a template and resources available to conduct future clinical trials. User and main processors run a program that permits the design and tracking at the user processor of a clinical trial through access by the user processor to the software template in the main database and modification of the template to formulate a new clinical trial. By accessing the template in the main database and modifying it to design a new clinical trial for use in the user processor, the result is that data entered into different user databases and uploaded to the main database during the subsequent trial will be compatible. Similarly, claims 19-38 and 42-44 require main and subsidiary processors to run a program that permits the design and tracking at the subsidiary user processor of a protocol of tasks to be completed for a clinical trial.

None of the applied references teaches or suggests the design of a clinical trial. Colon relates to the conduction of an already-designed clinical trial. During the trial a doctor inputs

patient data, and if the patient is eligible for the study, a study management center sends the doctor and initial suggested drug prescription. The doctor then has the option to confirm or adjust the prescription within the parameters of the clinical study protocol. The results are then sent to the host computer database for updating, and a hard copy of the drug prescription is printed.

Debusk also does not relate to the design of a clinical trial. Rather, Debusk relates to an information management system providing customized management of the use of medical resources (e.g., doctor time, equipment, and supplies) using user-configured software modules. Hospitals and health-care providers can buy an off-the-shelf software product that, through the use of the software modules, may be tailored to the facility's individuals needs. This software may be run on any stand-alone or network personal computer.

Edelson does not make up for the deficiencies of Colon and Debusk. Edelson relates to a prescription creation system, which divides a single prescription into two components for fulfillment of one portion quickly and locally at higher cost, and another portion by remote mail order at a cost savings.

Umen relates to a document production system for preparing documents and managing the composition of textual information pertaining to studies of medical products. More specifically, a computer-implemented document production system manages the composition of textual information pertaining to studies of a medical product, stores drug information within a data storage and retrieval system, and organizes the information in order to generate drug documents according to predetermined document formats.

Thus, it is clear that none of the applied references, either alone or in combination, suggests the design of a clinical trial, as required by the claims. Thus each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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